## General

#### Guideline Title

Obesity: identification, assessment and management of overweight and obesity in children, young people and adults.

## Bibliographic Source(s)

National Clinical Guideline Centre. Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Nov. 64 p. (Clinical guideline; no. 189).

#### **Guideline Status**

This is the current release of the guideline.

This guideline updates a previous version: National Collaborating Centre for Primary Care. Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. London (UK): National Institute for Health and Clinical Excellence; 2006 Dec. 2590 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Recommendations

# Major Recommendations

Note from the National Guideline Clearinghouse (NGC): The guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Recommendations are marked as [new 2014], [2006], or [2006, amended 2014]:

- [new 2014] indicates that the evidence has been reviewed and the recommendation has been added or updated
- [2006] indicates that the evidence has not been reviewed since 2006
- [2006, amended 2014] indicates that the evidence has not been reviewed since 2006, but either:
  - Changes have been made to the recommendation wording that change the meaning, or
  - NICE has made editorial changes to the original wording to clarify the action to be taken

The wording used in the recommendations in this guideline (for example words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation) and is defined at the end of the "Major Recommendations" field.

#### Generic Principles of Care

Adults

Equip specialist settings for treating people who are severely obese with, for example, special seating and adequate weighing and monitoring equipment. Ensure hospitals have access to specialist equipment – such as larger scanners and beds – when providing general care for people who are severely obese. [2006, amended 2014]

Discuss the choice of interventions for weight management with the person. The choice of intervention should be agreed with the person. [2006, amended 2014]

Tailor the components of the planned weight management programme to the person's preferences, initial fitness, health status and lifestyle. [2006]

#### Children

Aim to create a supportive environment<sup>2</sup> that helps a child who is overweight or who has obesity, and their family, make lifestyle changes. [2006, amended 2014]

Make decisions about the care of a child who is overweight or has obesity (including assessment and agreeing goals and actions) together with the child and family. Tailor interventions to the needs and preferences of the child and the family. [2006]

Ensure that interventions for children who are overweight or have obesity address lifestyle within the family and in social settings. [2006, amended 2014]

Encourage parents (or carers) to take main responsibility for lifestyle changes in children who are overweight or obese, especially if they are younger than 12 years. Take into account the age and maturity of the child, and the preferences of the child and the parents. [2006]

#### Adults and Children

Offer regular, non-discriminatory long-term follow-up by a trained professional. Ensure continuity of care in the multidisciplinary team through good record keeping. [2006]

#### Identification and Classification of Overweight and Obesity

Use clinical judgement to decide when to measure a person's height and weight. Opportunities include registration with a general practice, consultation for related conditions (such as type 2 diabetes and cardiovascular disease) and other routine health checks. [2006]

Measures of Overweight and Obesity

Use body mass index (BMI) as a practical estimate of adiposity in adults. Interpret BMI with caution because it is not a direct measure of adiposity. [2006, amended 2014]

Think about using waist circumference, in addition to BMI, in people with a BMI less than 35 kg/m<sup>2</sup>. [2006, amended 2014]

#### Children

Use BMI (adjusted for age and gender<sup>4</sup>) as a practical estimate of adiposity in children and young people. Interpret BMI with caution because it is not a direct measure of adiposity. [2006, amended 2014]

Waist circumference is not recommended as a routine measure. Use it to give additional information on the risk of developing other long-term health problems. [2006, amended 2014]

#### Adults and Children

Do not use bioimpedance as a substitute for BMI as a measure of general adiposity. [2006, amended 2014]

Classification of Overweight and Obesity

#### **Adults**

Define the degree of overweight or obesity in adults using the following table:

Classification	BMI (kg/m <sup>2</sup> )
Healthy weight	18.5–24.9
Overweight	25–29.9
Obesity I	30–34.9
Obesity II	35–39.9
Obesity III	40 or more

#### [2006]

Interpret BMI with caution in highly muscular adults as it may be a less accurate measure of adiposity in this group. Some other population groups, such as people of Asian family origin and older people, have comorbidity risk factors that are of concern at different BMIs (lower for adults of an Asian family origin and higher for older people<sup>3</sup>). Use clinical judgement when considering risk factors in these groups, even in people not classified as overweight or obese, using the classification in the recommendation above. [2006]

Base assessment of the health risks associated with being overweight or obese in adults on BMI and waist circumference as follows [2006]:

BMI Classification	Waist Circumference			
	Low	High	Very High	
Overweight	No increased risk	Increased risk	High risk	
Obesity 1	Increased risk	High risk	Very high risk	
For men, waist circumference of less than 94 cm is low, 94–102 cm is high and more than 102 cm is very high.  For women, waist circumference of less than 80 cm is low, 80–88 cm is high and more than 88 cm is very high.				

Give adults information about their classification of clinical obesity and the impact this has on risk factors for developing other long-term health problems. [2006]

Base the level of intervention to discuss with the patient initially as follows:

BMI Classification	Waist Circumference		mference	Comorbidities Present	
	Low	High	Very High		
Overweight	1	2	2	3	
Obesity I	2	2	2	3	
Obesity II	3	3	3	4	
Obesity III	4	4	4	4	
1	General advice on healthy weight and lifestyle				
2	Diet and physical activity				
3	Diet and physical activity; consider drugs				
4	Diet and physical activity; consider drugs; consider surgery				

The level of intervention should be higher for patients with comorbidities, regardless of their waist circumference. Adjust the approach as needed, depending on the person's clinical need and potential to benefit from losing weight. [2006]

#### Children

Relate BMI measurement in children and young people to the United Kingdom (UK) 1990 BMI charts<sup>4</sup> to give age- and gender-specific

information, [2006, amended 2014]

Tailored clinical intervention should be considered for children with a BMI at or above the 91st centile, depending on the needs of the individual child and family. [2006]

#### Assessment

#### Adults and Children

Make an initial assessment (see recommendations below), then use clinical judgement to investigate comorbidities and other factors to an appropriate level of detail, depending on the person, the timing of the assessment, the degree of overweight or obesity, and the results of previous assessments. [2006]

Manage comorbidities when they are identified; do not wait until the person has lost weight. [2006]

Offer people who are not yet ready to change the chance to return for further consultations when they are ready to discuss their weight again and willing or able to make lifestyle changes. Give them information on the benefits of losing weight, healthy eating and increased physical activity.

[2006]

Recognise that surprise, anger, denial or disbelief about their health situation may diminish people's ability or willingness to change. Stress that obesity is a clinical term with specific health implications, rather than a question of how people look; this may reduce any negative feelings.

#### During the consultation:

- · Assess the person's view of their weight and the diagnosis, and possible reasons for weight gain.
- Explore eating patterns and physical activity levels.
- · Explore any beliefs about eating, physical activity and weight gain that are unhelpful if the person wants to lose weight.
- Be aware that people from certain ethnic and socioeconomic backgrounds may be at greater risk of obesity, and may have different beliefs
  about what is a healthy weight and different attitudes towards weight management.
- Find out what the person has already tried and how successful this has been, and what they learned from the experience.
- Assess the person's readiness to adopt changes.
- Assess the person's confidence in making changes. [2006, amended 2014]

Give people and their families and/or carers information on the reasons for tests, how the tests are done, and their results and meaning. If necessary, offer another consultation to fully explore the options for treatment or discuss test results. [2006, amended 2014]

#### Adults

Take measurements (see recommendations above) to determine degree of overweight or obesity and discuss the implications of the person's weight. Then, assess:

- Any presenting symptoms
- Any underlying causes of being overweight or obese
- · Eating behaviours
- Any comorbidities (for example type 2 diabetes, hypertension, cardiovascular disease, osteoarthritis, dyslipidaemia and sleep apnoea)
- Any risk factors assessed using lipid profile (preferably done when fasting), blood pressure measurement and glycosylated haemoglogin (HbA<sub>1c</sub>) measurement
- The person's lifestyle (diet and physical activity)
- Any psychosocial distress
- Any environmental, social and family factors, including family history of overweight and obesity and comorbidities
- The person's willingness and motivation to change lifestyle
- The potential of weight loss to improve health
- Any psychological problems<sup>5</sup>
- Any medical problems and medication
- The role of family and care workers in supporting individuals with learning disabilities to make lifestyle changes [2006, amended 2014]

### Consider referral to tier 3 services<sup>6</sup> if:

• The underlying causes of being overweight or obese need to be assessed

- The person has complex disease states or needs that cannot be managed adequately in tier 2 (for example, the additional support needs of people with learning disabilities)
- Conventional treatment has been unsuccessful
- Drug treatment is being considered for a person with a BMI of more than 50 kg/m<sup>2</sup>
- Specialist interventions (such as a very-low-calorie diet) may be needed
- Surgery is being considered [2006, amended 2014]

#### Children

Assessment of comorbidity should be considered for children with a BMI at or above the 98th centile. [2006]

Take measurements to determine degree of overweight or obesity and raise the issue of weight with the child and family, then assess:

- Presenting symptoms and underlying causes of being overweight or obese
- Willingness and motivation to change
- Comorbidities (such as hypertension, hyperinsulinaemia, dyslipidaemia, type 2 diabetes, psychosocial dysfunction and exacerbation of conditions such as asthma)
- Any risk factors assessed using lipid profile (preferably done when fasting) blood pressure measurement and HbA<sub>1c</sub> measurement
- Psychosocial distress, such as low self-esteem, teasing and bullying<sup>5</sup>
- Family history of being overweight or obese and comorbidities
- The child and family's willingness and motivation to change lifestyle
- Lifestyle (diet and physical activity)
- · Environmental, social and family factors that may contribute to being overweight or obese, and the success of treatment
- Growth and pubertal status
- · Any medical problems and medication
- The role of family and care workers in supporting individuals with learning disabilities to make lifestyle changes [2006, amended 2014]

Consider referral to an appropriate specialist for children who are overweight or obese and have significant comorbidities or complex needs (for example, learning disabilities or other additional support needs). [2006, amended 2014]

In tier 3 services, assess associated comorbidities and possible causes for children and young people who are overweight or who have obesity. Use investigations such as:

- Blood pressure measurement
- Lipid profile, preferably while fasting
- Fasting insulin
- Fasting glucose levels and oral glucose tolerance test
- Liver function
- Endocrine function

Interpret the results of any tests used in the context of how overweight or obese the child is, the child's age, history of comorbidities, possible genetic causes and any family history of metabolic disease related to being overweight or obese. [2006, amended 2014]

Make arrangements for transitional care for children and young people who are moving from paediatric to adult services. [2006]

#### Lifestyle Interventions

#### Adults and Children

Multicomponent interventions are the treatment of choice. Ensure weight management programmes include behaviour change strategies (see recommendations below) to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake. [2006, amended 2014]

When choosing treatments, take into account:

- The person's individual preference and social circumstance and the experience and outcome of previous treatments (including whether there were any barriers)
- The person's level of risk, based on BMI and, where appropriate, waist circumference (see recommendations above)
- Any comorbidities [2006, amended 2014]

Document the results of any discussion. Keep a copy of the agreed goals and actions (ensure the person also does this), or put this in the person's notes. [2006, amended 2014]

Offer support depending on the person's needs, and be responsive to changes over time. [2006]

Ensure any healthcare professionals who deliver interventions for weight management have relevant competencies and have had specific training. [2006, amended 2014]

Provide information in formats and languages that are suited to the person. Use everyday, jargon-free language and explain any technical terms when talking to the person and their family or carers. Take into account the person's:

- Age and stage of life
- Gender
- Cultural needs and sensitivities
- Ethnicity
- Social and economic circumstances
- Specific communication needs (for example because of learning disabilities, physical disabilities or cognitive impairments due to neurological conditions) [2006, amended 2014]

Praise successes – however small – at every opportunity to encourage the person through the difficult process of changing established behaviour. [2006]

Give people who are overweight or obese, and their families and/or carers, relevant information on:

- Being overweight and obesity in general, including related health risks
- Realistic targets for weight loss; for adults, please see the NICE guideline on managing overweight and obesity in adults (NICE public health guideline 53)
- The distinction between losing weight and maintaining weight loss, and the importance of developing skills for both; advise them that the change from losing weight to maintenance typically happens after 6 to 9 months of treatment
- · Realistic targets for outcomes other than weight loss, such as increased physical activity and healthier eating
- Diagnosis and treatment options
- Healthy eating in general<sup>7</sup>
- Medication and side effects
- Surgical treatments
- Self-care
- Voluntary organisations and support groups and how to contact them

Ensure there is adequate time in the consultation to provide information and answer questions. [2006, amended 2014]

If a person (or their family or carers) does not feel this is the right time for them to take action, explain that advice and support will be available in the future whenever they need it. Provide contact details so that the person can get in touch when they are ready. [2006, amended 2014]

#### Adults

Encourage the person's partner or spouse to support any weight management programme. [2006]

Base the level of intensity of the intervention on the level of risk and the potential to gain health benefits (see recommendation above). [2006]

#### Children

Be aware that the aim of weight management programmes for children and young people can vary. The focus may be on either weight maintenance or weight loss, depending on the person's age and stage of growth. [2006, amended 2014]

Encourage parents of children and young people who are overweight or obese to lose weight if they are also overweight or obese. [2006]

#### Behavioural Interventions

#### Adults and Children

Deliver any behavioural intervention with the support of an appropriately trained professional. [2006]

#### Adults

Include the following strategies in behavioural interventions for adults, as appropriate:

- Self-monitoring of behaviour and progress
- Stimulus control
- Goal setting
- · Slowing rate of eating
- Ensuring social support
- Problem solving
- Assertiveness
- Cognitive restructuring (modifying thoughts)
- Reinforcement of changes
- Relapse prevention
- Strategies for dealing with weight regain [2006]

#### Children

Include the following strategies in behavioural interventions for children, as appropriate:

- Stimulus control
- Self-monitoring
- Goal setting
- Rewards for reaching goals
- Problem solving

Give praise to successes and encourage parents to role-model desired behaviours. [2006, amended 2014]

#### Physical Activity

#### Adults

Encourage adults to increase their level of physical activity even if they do not lose weight as a result, because of the other health benefits it can bring (for example, reduced risk of type 2 diabetes and cardiovascular disease). Encourage adults to do at least 30 minutes of moderate or greater intensity physical activity on 5 or more days a week. The activity can be in 1 session or several sessions lasting 10 minutes or more. [2006]

Advise that to prevent obesity, most people may need to do 45 to 60 minutes of moderate-intensity activity a day, particularly if they do not reduce their energy intake. Advise people who have been obese and have lost weight that they may need to do 60 to 90 minutes of activity a day to avoid regaining weight. [2006]

Encourage adults to build up to the recommended activity levels for weight maintenance, using a managed approach with agreed goals.

Recommend types of physical activity, including:

- Activities that can be incorporated into everyday life, such as brisk walking, gardening or cycling<sup>8</sup>
- Supervised exercise programmes
- Other activities, such as swimming, aiming to walk a certain number of steps each day, or stair climbing

#### [2006]

Take into account the person's current physical fitness and ability for all activities. Encourage people to also reduce the amount of time they spend inactive, such as watching television, using a computer or playing video games. [2006]

#### Children

Encourage children and young people to increase their level of physical activity, even if they do not lose weight as a result, because of the other health benefits exercise can bring (for example, reduced risk of type 2 diabetes and cardiovascular disease). Encourage children to do at least 60 minutes of moderate or greater intensity physical activity each day. The activity can be in 1 session or several sessions lasting 10 minutes or more. [2006]

Be aware that children who are already overweight may need to do more than 60 minutes' activity. [2006, amended 2014]

Encourage children to reduce inactive behaviours, such as sitting and watching television, using a computer or playing video games. [2006]

Give children the opportunity and support to do more exercise in their daily lives (for example, walking, cycling, using the stairs and active play<sup>8</sup>). Make the choice of activity with the child, and ensure it is appropriate to the child's ability and confidence. [2006]

Give children the opportunity and support to do more regular, structured physical activity (for example football, swimming or dancing). Make the choice of activity with the child, and ensure it is appropriate to the child's ability and confidence. [2006]

**Dietary** 

Adults and Children

Tailor dietary changes to food preferences and allow for a flexible and individual approach to reducing calorie intake. [2006]

Do not use unduly restrictive and nutritionally unbalanced diets, because they are ineffective in the long term and can be harmful. [2006, amended 2014]

Encourage people to improve their diet even if they do not lose weight, because there can be other health benefits. [2006]

Adults

The main requirement of a dietary approach to weight loss is that total energy intake should be less than energy expenditure. [2006]

Diets that have a 600 kcal/day deficit (that is, they contain 600 kcal less than the person needs to stay the same weight) or that reduce calories by lowering the fat content (low-fat diets), in combination with expert support and intensive follow-up, are recommended for sustainable weight loss. [2006]

Consider low-calorie diets (800–1600 kcal/day), but be aware these are less likely to be nutritionally complete. [2006, amended 2014]

Do not routinely use very-low-calorie diets (800 kcal/day or less) to manage obesity (defined as BMI over 30). [new 2014]

Only consider very-low-calorie diets, as part of a multicomponent weight management strategy, for people who are obese and who have a clinically-assessed need to rapidly lose weight (for example, people who need joint replacement surgery or who are seeking fertility services). Ensure that:

- The diet is nutritionally complete
- The diet is followed for a maximum of 12 weeks (continuously or intermittently)
- The person following the diet is given ongoing clinical support [new 2014]

Before starting someone on a very-low-calorie diet as part of a multicomponent weight management strategy:

- Consider counselling and assess for eating disorders or other psychopathology to make sure the diet is appropriate for them.
- Discuss the risks and benefits with them.
- Tell them that this is not a long-term weight management strategy, and that regaining weight may happen and is not because of their own or their clinician's failure.
- Discuss the reintroduction of food following a liquid diet with them [new 2014]

Provide a long-term multicomponent strategy to help the person maintain their weight after the use of a very-low-calorie diet (see recommendation above). [new 2014]

Encourage people to eat a balanced diet in the long term, consistent with other healthy eating advice<sup>7</sup>. [2006, amended 2014]

Children

A dietary approach alone is not recommended. It is essential that any dietary recommendations are part of a multicomponent intervention. [2006]

Any dietary changes should be age appropriate and consistent with healthy eating advice. [2006]

For overweight and obese children and young people, total energy intake should be below their energy expenditure. Changes should be sustainable. [2006, amended 2014]

#### Pharmacological Interventions

Adults

Consider pharmacological treatment only after dietary, exercise and behavioural approaches have been started and evaluated. [2006]

Consider drug treatment for people who have not reached their target weight loss or have reached a plateau on dietary, activity and behavioural changes. [2006]

Make the decision to start drug treatments after discussing the potential benefits and limitations with the person, including the mode of action, adverse effects and monitoring requirements, and the potential impact on the person's motivation. Make arrangements for appropriate healthcare professionals to offer information, support and counselling on additional diet, physical activity and behavioural strategies when drug treatment is prescribed. Provide information on patient support programmes. [2006, amended 2014]

#### Children

Drug treatment is not generally recommended for children younger than 12 years. [2006]

In children younger than 12 years, drug treatment may be used only in exceptional circumstances, if severe comorbidities are present. Prescribing should be started and monitored only in specialist paediatric settings. [2006, amended 2014]

In children aged 12 years and older, treatment with orlistat<sup>9</sup> is recommended only if physical comorbidities (such as orthopaedic problems or sleep apnoea) or severe psychological comorbidities are present. Treatment should be started in a specialist paediatric setting, by multidisciplinary teams with experience of prescribing in this age group. [2006, amended 2014]

Do not give orlistat to children for obesity unless prescribed by a multidisciplinary team with expertise in:

- Drug monitoring
- · Psychological support
- Behavioural interventions
- Interventions to increase physical activity
- Interventions to improve diet [2006, amended 2014]

Drug treatment may be continued in primary care for example with a shared care protocol if local circumstances and/or licensing allow. [2006, amended 2014]

#### Continued Prescribing and Withdrawal

Adults and Children

Pharmacological treatment may be used to maintain weight loss rather than to continue to lose weight. [2006]

If there is concern about micronutrient intake adequacy, a supplement providing the reference nutrient intake for all vitamins and minerals should be considered, particularly for vulnerable groups such as older people (who may be at risk of malnutrition) and young people (who need vitamins and minerals for growth and development). [2006]

Offer support to help maintain weight loss to people whose drug treatment is being withdrawn; if they did not reach their target weight, their self-confidence and belief in their ability to make changes may be low. [2006]

#### Adults

Monitor the effect of drug treatment and reinforce lifestyle advice and adherence through regular review. [2006, amended 2014]

Consider withdrawing drug treatment in people who have not reached weight loss targets (see recommendation below for details). [2006]

Rates of weight loss may be slower in people with type 2 diabetes, so less strict goals than those for people without diabetes may be appropriate. Agree the goals with the person and review them regularly. [2006]

Only prescribe orlistat as part of an overall plan for managing obesity in adults who meet one of the following criteria:

- A BMI of 28 kg/m<sup>2</sup> or more with associated risk factors
- A BMI of 30 kg/m<sup>2</sup> or more [2006]

Continue or listat therapy beyond 3 months only if the person has lost at least 5% of their initial body weight since starting drug treatment (see also recommendation above for advice on targets for people with type 2 diabetes). [2006]

Make the decision to use drug treatment for longer than 12 months (usually for weight maintenance) after discussing potential benefits and limitations with the person. [2006]

The co-prescribing of orlistat with other drugs aimed at weight reduction is not recommended. [2006]

#### Children

If or listat is prescribed for children, a 6- to 12-month trial is recommended, with regular review to assess effectiveness, adverse effects and adherence. [2006, amended 2014]

#### **Surgical Interventions**

Bariatric surgery is a treatment option for people with obesity if all of the following criteria are fulfilled:

- They have a BMI of 40 kg/m² or more, or between 35 kg/m² and 40 kg/m² and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight.
- All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss.
- The person has been receiving or will receive intensive management in a tier 3 service 10.
- The person is generally fit for anaesthesia and surgery.
- The person commits to the need for long-term follow-up.

See recommendations below for additional criteria to use when assessing children and adults. See also recommendations below for additional criteria for people with type 2 diabetes. [2006, amended 2014]

The hospital specialist and/or bariatric surgeon should discuss the following with people who are severely obese if they are considering surgery to aid weight reduction:

- The potential benefits
- The longer-term implications of surgery
- Associated risks
- Complications
- Perioperative mortality

The discussion should also include the person's family, as appropriate. [2006, amended 2014]

Choose the surgical intervention jointly with the person, taking into account:

- The degree of obesity
- Comorbidities
- The best available evidence on effectiveness and long-term effects
- The facilities and equipment available
- The experience of the surgeon who would perform the operation [2006]

Provide regular, specialist postoperative dietetic monitoring, including:

- Information on the appropriate diet for the bariatric procedure
- Monitoring of the person's micronutrient status
- Information on patient support groups
- Individualised nutritional supplementation, support and guidance to achieve long-term weight loss and weight maintenance [2006]

Arrange prospective audit so that the outcomes and complications of different procedures, the impact on quality of life and nutritional status, and the effect on comorbidities can be monitored in both the short and the long term. [2006, amended 2014]

The surgeon in the multidisciplinary team should:

• Have had a relevant supervised training programme

- Have specialist experience in bariatric surgery
- Submit data for a national clinical audit scheme [1] [2006, amended 2014]

#### Adults

In addition to the criteria listed above, bariatric surgery is the option of choice (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than  $50 \text{ kg/m}^2$  when other interventions have not been effective. [2006, amended 2014]

Orlistat may be used to maintain or reduce weight before surgery for people who have been recommended surgery as a first-line option, if it is considered that the waiting time for surgery is excessive. [2006, amended 2014]

Surgery for obesity should be undertaken only by a multidisciplinary team that can provide:

- Preoperative assessment, including a risk-benefit analysis that includes preventing complications of obesity, and specialist assessment for eating disorder(s)
- Information on the different procedures, including potential weight loss and associated risks
- Regular postoperative assessment, including specialist dietetic and surgical follow up (see recommendation under "Follow-up Care" below)
- Management of comorbidities
- Psychological support before and after surgery
- Information on, or access to, plastic surgery (such as apronectomy) when appropriate
- Access to suitable equipment, including scales, theatre tables, Zimmer frames, commodes, hoists, bed frames, pressure-relieving mattresses
  and seating suitable for people undergoing bariatric surgery, and staff trained to use them [2006]

Carry out a comprehensive preoperative assessment of any psychological or clinical factors that may affect adherence to postoperative care requirements (such as changes to diet) before performing surgery. [2006, amended 2014]

Revisional surgery (if the original operation has failed) should be undertaken only in specialist centres by surgeons with extensive experience because of the high rate of complications and increased mortality. [2006]

#### Children

Surgical intervention is not generally recommended in children or young people. [2006]

Bariatric surgery may be considered for young people only in exceptional circumstances, and if they have achieved or nearly achieved physiological maturity. [2006]

Surgery for obesity should be undertaken only by a multidisciplinary team that can provide paediatric expertise in:

- Preoperative assessment, including a risk-benefit analysis that includes preventing complications of obesity, and specialist assessment for eating disorder(s)
- Information on the different procedures, including potential weight loss and associated risks
- Regular postoperative assessment, including specialist dietetic and surgical follow up
- Management of comorbidities
- Psychological support before and after surgery
- Information on or access to plastic surgery (such as apronectomy) when appropriate
- Access to suitable equipment, including scales, theatre tables, Zimmer frames, commodes, hoists, bed frames, pressure-relieving mattresses
  and seating suitable for children and young people undergoing bariatric surgery, and staff trained to use them [2006]

Coordinate surgical care and follow-up around the child or yo	ung person and their family's needs. Comply with the approaches outlined in the
Department of Health's A call to action on obesity in England	. [2006, amended 2014]

Ensure all young people have had a comprehensive psychological, educational, family and social assessment before undergoing bariatric surgery. [2006, amended 2014]

Perform a full medical evaluation, including genetic screening or assessment before surgery to exclude rare, treatable causes of obesity. [2006]

Bariatric Surgery for People with Recent-onset Type 2 Diabetes

Offer an expedited assessment for bariatric surgery to people with a BMI of 35 or over who have recent-onset type 2 diabetes <sup>12</sup> as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent). [new 2014]

Consider an assessment for bariatric surgery for people with a BMI of 30–34.9 who have recent-onset type 2 diabetes <sup>12</sup> as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent). [new 2014]

Consider an assessment for bariatric surgery for people of Asian family origin who have recent-onset type 2 diabetes <sup>12</sup> at a lower BMI than other populations as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent). [new 2014]

#### Follow-up Care

Offer people who have had bariatric surgery a follow-up care package for a minimum of 2 years within the bariatric service. This should include:

- Monitoring nutritional intake (including protein and vitamins) and mineral deficiencies
- Monitoring for comorbidities
- Medication review
- Dietary and nutritional assessment, advice and support
- Physical activity advice and support
- Psychological support tailored to the individual
- Information about professionally-led or peer-support groups [new 2014]

After discharge from bariatric surgery service follow-up, ensure that all people are offered at least annual monitoring of nutritional status and appropriate supplementation according to need following bariatric surgery, as part of a shared care model of chronic disease management. [new 2014]

#### **Footnotes**

<sup>1</sup> Recommendations on the management of overweight and obesity in children and young people can be found in Managing overweight and obesity among children and young people:
lifestyle weight management services (NICE guideline PH47).
<sup>2</sup> The Guideline Development Group (GDG) noted that 'environment' could include settings other than the home, for example, schools.
<sup>3</sup> Further information on the use of BMI and waist circumference can be found in BMI and waist circumference – black, Asian and minority ethnic groups (NICE guideline PH46).
<sup>4</sup> Where available, BMI z-scores or the Royal College of Paediatrics and Child Health UK-World Health Organisation (WHO) growth charts may be used to calculate BMI in children and young people. The childhood and puberty close monitoring (CPCM) form may be used for longitudinal BMI monitoring in children over 4.
<sup>5</sup> Further recommendations can be found in Managing overweight and obesity among children and young people: lifestyle weight management services (NICE guideline PH47).
<sup>6</sup> For more information on tier 3 services, see NHS England's report on Joined up clinical pathways for obesity
<sup>7</sup> Further information on healthy eating can be found on NHS Choices
<sup>8</sup> Further recommendations can be found in Walking and cycling local measures to promote walking and cycling as forms of travel or recreation (NICE guideline PH41).
<sup>9</sup> At the time of publication (October 2014), orlistat did not have a UK marketing authorisation for use in children for this indication. The prescriber should follow relevant profession guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.
<sup>10</sup> For more information on tier 3 services, see NHS England's report on Joined up clinical pathways for obesity
<sup>11</sup> The National Bariatric Surgery Registry is now available to conduct national audit for a number of agreed outcomes.
<sup>12</sup> The GDG considered that recent-onset type 2 diabetes would include those people whose diagnosis has been made within a 10-year time frame.

#### **Definitions**:

#### Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group (GDG) makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the GDG is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

Interventions That Must (or Must Not) Be Used

The GDG usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally the GDG uses 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation

The GDG uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. Similar forms of words (for example, 'Do not offer...') are used when the GDG is confident that an intervention will not be of benefit for most patients.

Interventions That Could Be Used

The GDG uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Recommendation Wording in Guideline Updates

The National Institute for Health and Care Excellence (NICE) began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The Guidelines Manual' (January 2009). This does not apply to any recommendations ending [2006]. In particular, for recommendations labelled [2006] the word 'consider' may not necessarily be used to denote the strength of the recommendation.

## Clinical Algorithm(s)

The following clinical algorithms are provided the full version of the guideline (see the "Availability of Companion Documents" field):

- Very-low-calorie diets (VLCD)
- Bariatric surgery in people with type 2 diabetes
- Follow-up care packages after bariatric surgery

In addition, a NICE care pathway titled 'Obesity Overview' is available from the National Institute for Health and Care Excellence (NICE) Web site

# Scope

Disease/Condition(s	)
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Obesity and overweight

Other Disease/Condition(s) Addressed

Type 2 diabetes

# Guideline Category

Counseling

Diagnosis

Evaluation

Management

Prevention

Treatment
Clinical Specialty
Endocrinology
Family Practice
Internal Medicine
Nutrition
Pediatrics
Surgery
Intended Users
Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Hospitals
Nurses
Patients
Pharmacists
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Guideline Objective(s)
To offer best practice advice on the care of adults and children who are overweight or obese
Target Population
Adults, children and young people (aged 2 years or older) who are overweight or obese, including those with established comorbidities, and those

The following special groups, who have a high rate of morbidity resulting from being obese, are considered when there is good evidence of

• Black and minority ethnic groups

• People from lower socio-economic groups

with or without risk factors for other medical conditions

effectiveness of separate interventions targeted at these groups:

• Young people

Risk Assessment

- People with learning disabilities
- Older people

• People with type 2 diabetes

Note: The guideline does not cover people of a healthy weight, pregnant women or children under 2 years of age.

## Interventions and Practices Considered

#### Diagnosis/Evaluation

- 1. Family history
- 2. Assessment of symptoms, cause of overweight/obesity, and other factors
- 3. Body mass index (BMI) calculation
- 4. Waist circumference measurement
- 5. Classification of degree of overweight or obesity
- 6. Assessment of health risks
- 7. Assessment of comorbidities
- 8. Assessment of patient's willingness to change and potential for improvement

#### Management/Treatment

- 1. Management of comorbid conditions
- 2. Lifestyle interventions
  - Participation in a weight management program
  - Consideration of patient's preference and social circumstance, level of risk and any comorbidities, initial health, health status, and lifestyle
  - Documented discussion, providing copy of agreed goals and actions
  - Provision of information and support for patients and carers
- 3. Behavioural interventions delivered by trained professionals, including:
  - Self-monitoring of behaviour and progress
  - Stimulus control
  - Goal setting
  - Slowing rate of eating
  - Ensuring social support
  - Problem solving
  - Assertiveness
  - Cognitive restructuring (modifying thoughts)
  - Reinforcement of changes
  - Relapse prevention
  - Strategies for dealing with weight regain
  - Rewards for reaching goals (for children)
- 4. Physical activity
- 5. Dietary advice
- 6. Consideration of very-low-calorie diets in limited circumstances
- 7. Consideration of pharmacological interventions, including orlistat (not recommended routinely for children under 12 years)
- 8. Continued prescribing and withdrawal of drug treatment
- 9. Surgical interventions
  - Bariatric surgery
  - Revisional surgery
  - Considerations for people with recent-onset type 2 diabetes
- 10. Long-term follow-up
- 11. Referral to a specialist

# Major Outcomes Considered

• Change in weight and body mass index (BMI)

- Maintenance of weight loss
- Adverse events
- Health-related quality of life
- Glycaemic control in people with type 2 diabetes
- Remission in people with type 2 diabetes
- Long-term mortality

# Methodology

#### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Developing the Review Questions and Outcomes

Review questions were developed in a PICO framework (patient, intervention, comparison and outcome) for intervention reviews.

This use of a framework guided the literature searching process, critical appraisal and synthesis of evidence, and facilitated the development of recommendations by the Guideline Development Group (GDG). The review questions were drafted by the NCGC technical team and refined and validated by the GDG. The questions were based on the key clinical areas identified in the scope (see Appendix A in the full version of the guideline [see the "Availability of Companion Documents" field]).

A total of 5 review questions were identified. See Table 1 in the full version of the guideline.

Full literature searches, critical appraisals and evidence reviews were completed for all the specified review questions.

### Searching for Evidence

Clinical Literature Search

Systematic literature searches were undertaken to systematically identify all published clinical evidence relevant to the review questions. Searches were undertaken according to the parameters stipulated within "The Guidelines Manual" (2012) (see the "Availability of Companion Documents" field). Databases were searched using relevant medical subject headings, free-text terms and study-type filters where appropriate. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in English. All searches were conducted in MEDLINE, EMBASE, and The Cochrane Library. In addition, PsycINFO was used for the questions on very-low-calorie diets and care packages after bariatric surgery.

Search strategies were quality assured by cross-checking reference lists of highly relevant papers, analysing search strategies in other systematic reviews, and asking GDG members to highlight any additional studies. The questions, the study types applied, the databases searched and the years covered can be found in Appendix F in the full version of the guideline.

The titles and abstracts of records retrieved by the searches were sifted for relevance, with potentially significant publications obtained in full text. These were assessed against the inclusion criteria.

Health Economic Literature Search

Systematic literature searches were also undertaken to identify health economic evidence within published literature relevant to the review

questions. The evidence was identified by conducting searches using the population and intervention terms in the National Health Service Economic Evaluation Database (NHS EED), the Health Technology Assessment database (HTA) and the Health Economic Evaluations Database (HEED) from 2006 onwards. Additionally, the search was run on MEDLINE and EMBASE using a specific economic filter, population and intervention terms, from 2006, to ensure recent publications that had not yet been indexed by the economic databases were identified. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in English.

The health economic search strategies are included in Appendix F in the full version of the guideline.

#### Evidence of Effectiveness

The evidence was reviewed following the steps shown schematically in Figure 1 in the full version of the guideline:

- Potentially relevant studies were identified for each review question from the relevant search results by reviewing titles and abstracts. Full
  papers were then obtained.
- Full papers were reviewed against pre-specified inclusion and exclusion criteria to identify studies that addressed the review question in the appropriate population (review protocols are included in Appendix C in the full version of the guideline).

#### Inclusion and Exclusion Criteria

The inclusion and exclusion of studies was based on the review protocols, which can be found in Appendix C in the full version of the guideline. Excluded studies by review question (with the reasons for their exclusion) are listed in Appendix J in the full version of the guideline. The GDG was consulted about any uncertainty regarding inclusion or exclusion.

The guideline population was people who are overweight defined as a body mass index (BMI) 25-29.9 (kg/m²) or obese defined as a BMI 30 or over (kg/m²). The review population included adults and children over 2 years old. The only exception was for the question on follow-up care packages after bariatric surgery which included adults and young people (post puberty) as prepuberty children would need different follow-up care.

For the review question on bariatric surgery in type 2 diabetes, the review population included overweight and obese adults with recent-onset type 2 diabetes. Recent-onset type 2 diabetes was defined as a duration of less than or equal to 10 years.

Literature reviews, posters, letters, editorials, comment articles, unpublished studies and studies not in English were excluded.

The review protocols are presented in Appendix C in the full version of the guideline.

#### Type of Studies

For most intervention reviews in this guideline, parallel randomised controlled trials (RCTs) were included because they are considered the most robust type of study design that could produce an unbiased estimate of the intervention effects. If there was limited evidence from RCTs, a conference abstract search was completed and authors were contacted for further information of any relevant studies. Please refer to Appendix C in the full version of the guideline for full details on the study design of studies selected for each review question.

#### Evidence of Cost-effectiveness

The GDG is required to make decisions based on the best available evidence of both clinical and cost-effectiveness. Guideline recommendations should be based on the expected costs of the different options in relation to their expected health benefits (that is, their 'cost-effectiveness') rather than the total implementation cost. Thus, if the evidence suggests that a strategy provides significant health benefits at an acceptable cost per patient treated, it should be recommended even if it would be expensive to implement across the whole population.

Evidence on cost-effectiveness related to the key clinical issues being addressed in the guideline was sought. The health economist:

- Undertook a systematic review of the published economic literature
- Undertook original health economic analyses where appropriate

#### Literature Review

#### The health economist:

- Identified potentially relevant studies for each review question from the economic search results by reviewing titles and abstracts. Full papers
  were then obtained.
- Reviewed full papers against pre-specified inclusion and exclusion criteria to identify relevant studies (see below for details).

Inclusion and Exclusion Criteria

Full economic evaluations (studies comparing costs and health consequences of alternative courses of action: cost—utility, cost-effectiveness, cost—benefit and cost—consequence analyses) and comparative costing studies that addressed the review question in the relevant population were considered potentially includable as economic evidence.

Studies that only reported cost per hospital (not per patient), or only reported average cost effectiveness without disaggregated costs and effects, were excluded. Literature reviews, abstracts, posters, letters, editorials, comment articles, unpublished studies and studies not in English were excluded.

Remaining studies were prioritised for inclusion based on their relative applicability to the development of this guideline and the study limitations. For example, if a high quality, directly applicable UK analysis was available, then other less relevant studies may not have been included. Where exclusions occurred on this basis, this is noted in the relevant section.

For more details about the assessment of applicability and methodological quality see the economic evaluation checklist (Appendix F in 'The Guidelines Manual" and the health economics review protocol in Appendix C in the full version of the guideline).

When no relevant economic studies were found from the economic literature review, relevant UK NHS unit costs related to the compared interventions were presented to the GDG to inform the possible economic implications of the recommendations.

#### Number of Source Documents

Refer to Appendix D in the full version of the guideline (see the "Availability of Companion Documents" field) for flow diagrams of clinical selection, which detail the total number of studies included for each guideline topic.

Refer to Appendix E in the full version of the guideline for a flow diagram of economic article selection for the guideline.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

# Rating Scheme for the Strength of the Evidence

Overall Quality of Outcome Evidence in Grading of Recommendations Assessment, Development and Evaluation (GRADE)

Level	Description
High	Further research is very unlikely to change confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate
Very Low	Any estimate of effect is very uncertain

# Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

# Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The guideline was developed by the National Clinical Guideline Centre (NCGC) on

behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

#### Evidence of Effectiveness

The evidence was reviewed following the steps shown schematically in Figure 1 in the full version of the guideline:

- Relevant studies were critically appraised using the appropriate checklist as specified in The Guidelines Manual (see the "Availability of Companion Documents" field).
- Key information was extracted on the study's methods, PICO (patient, intervention, comparison and outcome) factors and results. These were presented in summary tables (in each review chapter) and evidence tables (see Appendix G in the full version of the guideline [see the "Availability of Companion Documents" field]).
- Summaries of evidence were generated by outcome (included in the relevant review chapters) and were presented in Guideline Development Group (GDG) meetings:
  - Randomised studies: data were meta-analysed where appropriate and reported in Grading of Recommendations Assessment, Development, and Evaluation (GRADE) profiles (for intervention reviews).

A sample of the above stages of the reviewing process was quality assured by a second reviewer to eliminate any potential of reviewer bias or error.

Methods of Combining Clinical Studies

Data Synthesis for Intervention Reviews

Where possible, meta-analyses were conducted to combine the results of studies for each review question using Cochrane Review Manager (RevMan5) software. Fixed-effects (Mantel-Haenszel) techniques were used to calculate risk ratios (relative risk) for the binary outcomes: reoperation rate, mortality, remission of type 2 diabetes, reduction of diabetic medication, withdrawals, depression tendencies, constipation, gallstones and diarrhoea.

For continuous outcomes, measures of central tendency (mean) and variation (standard deviation) were required for meta-analysis. Data for continuous outcomes (% weight change [kg or body mass index (BMI)], weight change [kg or BMI], improvement in glycaemic control, use of diabetic medication, health related quality of life, psychological well-being, improvement in physical activity, depression score and binge eating) were analysed using an inverse variance method for pooling weighted mean differences and, where the studies had different scales, standardised mean differences were used. A generic inverse variance option in RevMan5 was used if any studies reported solely the summary statistics and 95% confidence interval (95% CI) or standard error; this included any hazard ratios reported. However, in cases where standard deviations were not reported per intervention group, the standard error (SE) for the mean difference was calculated from other reported statistics (p values or 95% CIs); meta-analysis was then undertaken for the mean difference and SE using the generic inverse variance method in RevMan5. When the only evidence was based on studies that summarised results by presenting medians (and interquartile ranges), or only p values were given, this information was assessed in terms of the study's sample size and was included in the GRADE tables without calculating the relative or absolute effects. Consequently, aspects of quality assessment such as imprecision of effect could not be assessed for evidence of this type.

When reported time to event data was presented as a hazard ratio.

Stratified analyses were predefined for the review questions at the protocol stage when the GDG identified that these strata are different in terms of biological and clinical characteristics and the interventions were expected to have a different effect on subpopulations. Strata included:

- Different BMI categories
- People with learning disabilities
- Young people (puberty onwards)

For more information on strata refer to the protocols (see Appendix C in the full version of the guideline).

Statistical heterogeneity was assessed by visually examining the forest plots, and by considering the chi-squared test for significance at p<0.1 or an I-squared inconsistency statistic (with an I-squared value of more than 50% indicating considerable heterogeneity). Where considerable heterogeneity was present, reviewers carried out predefined subgroup analyses detailed in the protocols (see Appendix C in the full version of the guideline).

Assessments of potential differences in effect between subgroups were based on the chi-squared tests for heterogeneity statistics between subgroups. If no sensitivity analysis was found to completely resolve statistical heterogeneity then a random-effects (DerSimonian and Laird) model

was employed to provide a more conservative estimate of the effect.

The means and standard deviations of continuous outcomes were required for meta-analysis. However, in cases where standard deviations were not reported, the standard error was calculated if the p values or 95% CIs were reported and meta-analysis was undertaken with the mean and standard error using the generic inverse variance method in RevMan5. Where p values were reported as 'less than', a conservative approach was undertaken. For example, if p value was reported as 'p≤0.001', the calculations for standard deviations will be based on a p value of 0.001. If these statistical measures were not available then the methods described in Section 16.1.3 of the Cochrane Handbook (September 2009) 'Missing standard deviations' were applied as the last resort.

For interpretation of the binary outcome results, differences in the absolute event rate were calculated using the GRADEpro software, for the median event rate across the control arms of the individual studies in the meta-analysis. Absolute risk differences were presented in the GRADE profiles and in clinical summary of findings tables, for discussion with the GDG.

For binary outcomes, absolute event rates were also calculated using the GRADEpro software using event rate in the control arm of the pooled results.

Appraising the Quality of Evidence by Outcomes

The evidence for outcomes from the included RCTs and, where appropriate, observational studies were evaluated and presented using an
adaptation of the 'GRADE toolbox' developed by the international GRADE working group (http://www.gradeworkinggroup.org/
). The software developed by the GRADE working group (GRADEpro) was used to assess the quality of each outcome,
taking into account individual study quality factors and the meta-analysis results. Results were presented in GRADE profiles ('GRADE tables'),
which consist of 2 sections: the 'Clinical evidence profile' table includes details of the quality assessment while the 'Clinical evidence summary of
findings' table includes pooled outcome data, where appropriate, an absolute measure of intervention effect and the summary of quality of evidence
for that outcome. In this table, the columns for intervention and control indicate summary measures and measures of dispersion (such as mean and
standard deviation or median and range) for continuous outcomes and frequency of events (n/N: the sum across studies of the number of patients
with events divided by sum of the number of completers) for binary outcomes.

The evidence for each outcome was examined separately for the quality elements listed and defined in Table 2 in the full version of the guideline. Each element was graded using the quality levels listed in Table 3 in the full version of the guideline. The main criteria considered in the rating of these elements are discussed below. Footnotes were used to describe reasons for grading a quality element as having serious or very serious problems. The ratings for each component were summed to obtain an overall assessment for each outcome (see the "Rating Scheme for the Strength of the Evidence" field).

#### Grading the Quality of Clinical Evidence

After results were pooled, the overall quality of evidence for each outcome was considered. The following procedure was adopted when using GRADE:

- 1. A quality rating was assigned, based on the study design. RCTs start as High, observational studies as Low, and uncontrolled case series as Low or Very low.
- 2. The rating was then downgraded for the specified criteria: risk of bias (study limitations), inconsistency, indirectness, imprecision and publication bias. These criteria are detailed in the full version of the guideline. Evidence from observational studies (which had not previously been downgraded) was upgraded if there was: a large magnitude of effect, a dose–response gradient, and if all plausible confounding would reduce a demonstrated effect or suggest a spurious effect when results showed no effect. Each quality element considered to have 'serious' or 'very serious' risk of bias was rated down by 1 or 2 points respectively.
- 3. The downgraded or upgraded marks were then summed and the overall quality rating was revised. For example, all RCTs started as High and the overall quality became Moderate, Low or Very low if 1, 2 or 3 points were deducted respectively.
- 4. The reasons or criteria used for downgrading were specified in the footnotes.

See Sections 3.4.6 to 3.4.9 in the full version of the guideline for information on risk of bias, inconsistency, indirectness, and imprecision.

#### Assessing Clinical Importance

The GDG assessed the evidence by outcome in order to determine if there was, or potentially was, a clinically important benefit, a clinically important harm or no clinically important difference between interventions. To facilitate this, binary outcomes were converted into absolute risk differences (ARDs) using GRADEpro software: the median control group risk across studies was used to calculate the ARD and its 95% CI from the pooled risk ratio.

The assessment of benefit, harm, or no benefit or harm was based on the point estimate of absolute effect for intervention studies in relation to the comparison (or control) event rate.

This assessment was carried out by the GDG for each critical outcome, and an evidence summary table was produced to compile the GDG's assessments of clinical importance per outcome, alongside the evidence quality and the uncertainty in the effect estimate (imprecision).

#### **Evidence Statements**

Evidence statements are summary statements that are presented after the GRADE profiles, summarising the key features of the clinical effectiveness evidence presented. The wording of the evidence statements reflects the certainty or uncertainty in the estimate of effect. The evidence statements are presented by outcome and encompass the following key features of the evidence:

- The number of studies and the number of participants for a particular outcome
- A brief description of the participants
- An indication of the direction of effect (if one treatment is beneficial or harmful compared to the other, or whether there is no difference between the 2 tested treatments)
- A description of the overall quality of evidence (GRADE overall quality)

#### Evidence of Cost-effectiveness

The GDG is required to make decisions based on the best available evidence of both clinical and cost effectiveness. Guideline recommendations should be based on the expected costs of the different options in relation to their expected health benefits (that is, their 'cost-effectiveness') rather than the total implementation cost. Thus, if the evidence suggests that a strategy provides significant health benefits at an acceptable cost per patient treated, it should be recommended even if it would be expensive to implement across the whole population.

Evidence on cost effectiveness related to the key clinical issues being addressed in the guideline was sought. The health economist:

- Undertook a systematic review of the published economic literature
- Undertook original health economic analyses where appropriate

#### Literature Review

#### The health economist:

- Critically appraised relevant studies using the economic evaluations checklist as specified in The Guidelines Manual (see the "Availability of Companion Documents" field).
- Extracted key information about the studies' methods and results into evidence tables (included in Appendix H in the full version of the guideline).
- Generated summaries of the evidence in NICE economic evidence profiles (included in the relevant chapter for each review question) see below for details.

#### NICE Economic Evidence Profiles

The NICE economic evidence profile has been used to summarise cost and cost-effectiveness estimates. The economic evidence profile shows an assessment of applicability and methodological quality for each economic evaluation, with footnotes indicating the reasons for the assessment. These assessments were made by the health economist using the economic evaluation checklist from The Guidelines Manual (see the "Availability of Companion Documents" field). It also shows the incremental costs, incremental effects (for example, quality-adjusted life years [QALYs]) and incremental cost-effectiveness ratio for the base case analysis in the evaluation, as well as information about the assessment of uncertainty in the analysis. See Table 6 in the full version of the guideline for more details.

If a non-UK study was included in the profile, the results were converted into pounds sterling using the appropriate purchasing power parity.

### Methods Used to Formulate the Recommendations

**Expert Consensus** 

Informal Consensus

## Description of Methods Used to Formulate the Recommendations

Note from the National Guideline Clearinghouse (NGC): The guideline was developed by the National Clinical Guideline Centre (NCGC) on behalf of the National Institute for Health and Care Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

A multidisciplinary Guideline Development Group (GDG) comprising professional group members and consumer representatives of the main stakeholders developed this guideline. The GDG was convened by the NCGC and chaired by Dr Peter Barry in accordance with guidance from NICE. The group met every 4 weeks during the development of the guideline. Staff from the NCGC provided methodological support and guidance for the development process. The team working on the guideline included a project manager, systematic reviewers, health economists and information scientists. They undertook systematic searches of the literature, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate and drafted the guideline in collaboration with the GDG.

#### Amendments to 2006 Text

All text and recommendations from the previous guideline, CG43, that has not been updated (therefore review questions have not been generated and evidence has not been searched for) was left unchanged. Amendments to recommendations are detailed in Appendix Q in the full version of the guideline.

#### Developing Recommendations

Over the course of the guideline development process, the GDG was presented with:

- Evidence tables of the clinical and economic evidence reviewed from the literature. All evidence tables are in Appendices G and H in the full version of the guideline (see the "Availability of Companion Documents" field). Excluded evidence can be found in Appendices J and K in the full version of the guideline.
- Summary of clinical and economic evidence and quality (as presented in Chapters 6-8 in the full version of the guideline)
- Forest plots (see Appendix I in the full version of the guideline).

Recommendations were drafted on the basis of the GDG interpretation of the available evidence, taking into account the balance of benefits, harms and costs between different courses of action. Firstly, the net benefit over harm (clinical effectiveness) was considered, focusing on the critical outcomes. When this was done informally, the GDG took into account the clinical benefits and harms when one intervention was compared with another. The assessment of net benefit was moderated by the importance placed on the outcomes (the GDG's values and preferences), and the confidence the GDG had in the evidence (evidence quality). Secondly, it was assessed whether the net benefit justified any differences in costs.

When clinical and economic evidence was of poor quality, conflicting, or absent, the GDG drafted recommendations based on their expert opinion. The considerations for making consensus-based recommendations include the balance between potential harms and benefits, the economic costs compared to the economic benefits, current practices, and recommendations made in other relevant guidelines, patient preferences and equality issues. The GDG also considered whether the uncertainty was sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation.

The wording of recommendations was agreed by the GDG and focused on the following factors:

- The actions health professionals need to take
- The information readers need to know
- The strength of the recommendation (for example the word 'offer' was used for strong recommendations and 'consider' for weak recommendations)
- The involvement of patients (and their carers if needed) in decisions on treatment and care
- · Consistency with NICE's standard advice on recommendations about drugs, waiting times and ineffective interventions

The main considerations specific to each recommendation are outlined in the 'Recommendations and link to evidence' sections within each chapter.

# Rating Scheme for the Strength of the Recommendations

### Strength of Recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group (GDG) makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some

interventions, the GDG is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

Interventions That Must (or Must Not) Be Used

The GDG usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally the GDG uses 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions That Should (or Should Not) Be Used – a 'Strong' Recommendation

The GDG uses 'offer' (and similar words such as 'refer' or 'advise') when confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. Similar forms of words (for example, 'Do not offer...') are used when the GDG is confident that an intervention will not be of benefit for most patients.

Interventions That Could Be Used

The GDG uses 'consider' when confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Recommendation Wording in Guideline Updates

The National Institute for Health and Care Excellence (NICE) began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of The Guidelines Manual (January 2009). This does not apply to any recommendations ending [2006]. In particular, for recommendations labelled [2006] the word 'consider' may not necessarily be used to denote the strength of the recommendation.

## Cost Analysis

Undertaking New Health Economic Analysis

As well as reviewing the published economic literature for each review question, new economic analysis was considered by the health economist in selected areas. Priority areas for new health economic analysis were discussed with the Guideline Development Group (GDG) after formation of the review questions and consideration of the available health economic evidence. It was agreed by the GDG that for the review question concerning bariatric surgery for early onset type 2 diabetes the cost-effectiveness evidence that existed was sufficient to base recommendations on. For very-low-calorie diets and follow-up care after surgery the GDG agreed that the long-run data needed to populate a model does not exist. Therefore as the results on any model would be largely driven by assumptions rather than clinical evidence no original economic analysis was conducted. To fully consider cost-effectiveness, quality of life studies were incorporated into threshold analysis to see how effective interventions would need to be to be considered cost effective.

#### Cost-effectiveness Criteria

The National Institute for Health and Care Excellence (NICE) report 'Social value judgements: principles for the development of NICE guidance' sets out the principles that GDGs should consider when judging whether an intervention offers good value for money. In general, an intervention was considered to be cost effective if either of the following criteria applied (given that the estimate was considered plausible):

- The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies)
- The intervention cost less than £20,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy.

If the GDG recommended an intervention that was estimated to cost more than £20,000 per QALY gained, or did not recommend one that was estimated to cost less than £20,000 per QALY gained, the reasons for this decision are discussed explicitly in the 'Recommendations and link to evidence' section of the relevant chapter, with reference to issues regarding the plausibility of the estimate or to the factors set out in 'Social value judgements: principles for the development of NICE guidance'.

If a study reported the cost per life year gained but not QALYs, the cost per QALY gained was estimated by multiplying by an appropriate utility estimate to aid interpretation. The estimated cost per QALY gained is reported in the economic evidence profile with a footnote detailing the life-years gained and the utility value used. When QALYs or life years gained are not used in the analysis, results are difficult to interpret unless one

strategy dominates the others with respect to every relevant health outcome and cost.

In the Absence of Economic Evidence

When no relevant published studies were found, and a new analysis was not prioritised, the GDG made a qualitative judgement about cost effectiveness by considering expected differences in resource use between options and relevant UK NHS unit costs, alongside the results of the clinical review of effectiveness evidence.

### Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

This guidance is subject to a 4-week public consultation and feedback as part of the quality assurance and peer review of the document. All comments received from registered stakeholders are responded to in turn and posted on the National Institute for Health and Care Excellence (NICE) Web site after publication of the guideline.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

# Benefits/Harms of Implementing the Guideline Recommendations

#### Potential Benefits

Appropriate identification, assessment and management of overweight and obesity in children, young people and adults

Refer to the "Trade-off between clinical benefits and harms" sections in the full version of the guideline (see the "Availability of Companion Documents" field) for benefits of specific interventions.

#### **Potential Harms**

Side effects of medications used in treatment of obesity, complications of bariatric surgery, and adverse effects arising from very-low-calorie diets

Refer to the "Trade-off between clinical benefits and harms" sections in the full version of the guideline (see the "Availability of Companion Documents" field) for harms of specific interventions.

# **Qualifying Statements**

# **Qualifying Statements**

This guidance represents the view of the National Institute for Health and Care Excellence (NICE), which was arrived at after careful
consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical
judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate

to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of product characteristics of any drugs. • Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the Department of Health's advice on consent (or, in Wales, advice on consent from the Welsh Government ). If someone does not have capacity to make decisions, healthcare professionals should follow the code of practice that accompanies the Mental Capacity Act and the supplementary code of practice on deprivation of liberty safeguards NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in Patient experience in adult NHS services • NICE has also produced guidance on the components of good service user experience. All healthcare professionals and social care practitioners working with people using adult NHS mental health services should follow the recommendations in Service user experience in • If a young person is moving between paediatric and adult services, care should be planned and managed according to the best practice guidance described in the Department of Health's Transition: getting it right for young people Adult and paediatric healthcare teams should work jointly to provide assessment and services to young people who are overweight or obese. Support and management should be reviewed throughout the transition process, and there should be clarity about who is the lead clinician to ensure continuity of care. • For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision. • This guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual • This guideline recommends some drugs for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information. Where recommendations have been made for the use of drugs outside their licensed indications ('off-label use'), these drugs are marked with a footnote in the recommendations. Implementation of the Guideline Description of Implementation Strategy Implementation tools and resources to help clinicians put the guideline into practice are available on the National Institute for Health and Care Excellence (NICE) Web site (see also the "Availability of Companion Documents" field). **Implementation Tools** Clinical Algorithm Mobile Device Resources

Patient Resources

Resources

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

### **IOM Care Need**

Getting Better

Staying Healthy

#### **IOM Domain**

Effectiveness

Patient-centeredness

# Identifying Information and Availability

## Bibliographic Source(s)

National Clinical Guideline Centre. Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Nov. 64 p. (Clinical guideline; no. 189).

## Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2006 Dec (revised 2014 Nov)

## Guideline Developer(s)

National Guideline Centre - National Government Agency [Non-U.S.]

## Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

### Guideline Committee

Guideline Development Group (GDG)

# Composition of Group That Authored the Guideline

Guideline Development Group Members: Peter Barry (Chair), Intensivist Paediatrician, Leicester Royal Infirmary; Rachel Batterham, Reader in Diabetes, Endocrinology and Obesity, Honorary Consultant, Head of Obesity and Bariatric Services, University College Hospital NHS Trust, Head of the Centre for Obesity Research, University College London; Alexandra Blakemore, Patient and carer member; Ken Clare, Patient and

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## Financial Disclosures/Conflicts of Interest

At the start of the guideline development process all Guideline Development Group (GDG) members declared interests including consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared arising conflicts of interest. Members were either required to withdraw completely or for part of the discussion if their declared interest made it appropriate. The details of declared interests and the actions taken are shown in Appendix B in the full version of the guideline (see the "Availability of Companion Documents" field).

#### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Collaborating Centre for Primary Care. Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. London (UK): National Institute for Health and Clinical Excellence; 2006 Dec. 2590 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic copies: Available from the National Institute for Health an	d Care Excellence (NICE)	Web site	. Also available
for download in ePub and eBook formats from the NICE Web site			

# Availability of Companion Documents

The following are available:

KNOWING the Avenue.
Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. Full guideline. Londor (UK): National Institute for Health and Care Excellence; 2014 Nov. 154 p. (Clinical guideline; no. 189). Electronic copies: Available from
the National Institute for Health and Care Excellence (NICE) Web site
Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. Appendices. London
(UK): National Institute for Health and Care Excellence; 2014 Nov. (Clinical guideline; no. 189). Electronic copies: Available from the
NICE Web site
Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. Baseline assessment
tool. London (UK): National Institute for Health and Care Excellence; 2014 Nov. (Clinical guideline; no. 189). Electronic copies: Availab
from the NICE Web site
Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. Costing report. London
(UK): National Institute for Health and Care Excellence; 2014 Dec. 35 p. (Clinical guideline; no. 189). Electronic copies: Available from the
NICE Web site
Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. Costing template.
London (UK): National Institute for Health and Care Excellence; 2014 Dec. (Clinical guideline; no. 189). Electronic copies: Available from
the NICE Web site

• The guidelines manual 2012. London (UK): National Institute for Health and Care Excellence (NICE); 2012 Nov. Electronic copies:

Available from the NICE Web site .	
Patient Resources	
The following is available:	
Obesity: identification, assessment and management of overweight and obesity in children, y public. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Nov the National Institute for Health and Care Excellence (NICE) Web site eBook formats from the NICE Web site	
Please note: This patient information is intended to provide health professionals with information to share with their patied diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific me and their representatives to review this material and then to consult with a licensed health professional for evaluation of treasurements to their personal medical questions. This patient information has been derived and prepared from a guideline for he publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurate.	dical advice for particular patients. Rather we urge patients eatment options suitable for them as well as for diagnosis and ealth care professionals included on NGC by the authors or
NGC Status	
This NGC summary was completed by ECRI on March 31, 2009. This summary was updated by the U.S. Food and Drug Administration advisory on Meridia. This summary was updated by ECRI Food and Drug Administration advisory on Orlistat. This summary was updated by ECRI Institute	I Institute on July 20, 2010 following the U.S.
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